



December 21, 2001

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Ref: Docket Number 00D-1538
Draft "Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Validation" August 2001

Dear Sir/Madam,

Amgen Inc. appreciates the opportunity to provide comments on the above referenced Draft Guidance for Industry.

Although the August 2001 Draft "Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Validation" does provide additional information and guidance to industry regarding compliance with the validation requirements of 21 CFR Part 11, additional clarification is requested.

Amgen's specific comments are as follows:

Section 5.1 "System Requirement Specifications":

The section titled "System Requirement Specifications" contains several references for which we seek further clarification (e.g., "system design requirements and specifications," and "end user requirement specifications"). These terms appear to refer to various documents, however, they are not defined and it is unclear if the guidance is referring to the same or different documents. Additional clarification is requested.

The section states that "Other factors not specifically addressed in part 11 may also impact on electronic record trustworthiness, integrity." One example of trustworthiness and integrity (i.e., scanning processes) is given. Amgen believes that additional examples of trustworthiness and integrity requirements would be beneficial.

Section 5.4.2 "Software testing should include":

The term "program build testing" is used. Amgen requests further clarification of this term.

Thank you again for the opportunity to provide comments on the agency's draft guidance documents. If you have any questions, feel free to contact me at (805) 447-4478.

Sincerely,

00D-1538

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Kimball Hall
Director, Quality Compliance